

REMARKS

Summary Of The Office Action & Formalities

Status of Claims

Claims 1-10 are all the claims pending in the application. By this Amendment, Applicant is amending claim 1.

Claim to Foreign Priority

Applicant thanks the Examiner for acknowledging the claim to foreign priority and for confirming that the certified copy of the priority document was received.

Drawings

Applicant respectfully requests that the Examiner acknowledge that the drawings have been accepted.

Specification

The disclosure is objected to because it lacks subheadings. Applicant is amending the specification to overcome this objection.

Also, the abstract of the disclosure is objected to as being too long. Applicant is amending the abstract to overcome this objection.

Claim Rejections - § 112

Claims 1-10 are rejected under 35 U.S.C. § 112, second paragraph, for the reason set forth at page 3 of the Office Action. Particularly, the Examiner states that the use of the term “preferably” in claim 1 renders the claims indefinite. In response, Applicant is amending the claims to overcome this rejection.

Allowable Subject Matter

Applicant thanks the Examiner for indicating that claims 5-10 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Since the rejection of the corresponding base claims are believed to be overcome, Applicant has not placed claims 5-10 in independent form at this time.

Art Rejections

1. Claims 1-4 are rejected under 35 U.S.C. § 102(e) as being anticipated by Genova et al. (WO 01/70319).
2. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Casper et al. (US 5,826,571).

Applicant respectfully traverses.

Claim Rejections - 35 U.S.C. § 102

1. *Claims 1-4 In View Of Genova et al. (WO 01/70319).*

In rejecting claims 1-4 in view of Genova et al. (WO 01/70319), the grounds of rejection state:

The Genova et al. reference discloses an inhalation actuated device comprising a reservoir 73, a metering valve 76, an automatic trigger mechanism 90 and a pneumatic brake device (proximate reference numeral 91), as claimed.

Office Action at page 4.

Claim 1 recites a valve-member release system that is actuated automatically and immediately when the valve member reaches its dispensing position. In contrast, the alleged valve-member release system of Genova is not actuated automatically and immediately when the

valve member reaches its dispensing position. Genova discloses a device for temporary blocking the valve in a depressed position. One of the main characteristic of Genova is that it provides for temporary blocking (page 7, line 28 - page 9, line 3; page 9, lines 3-6; page 16, lines 23-30; revs. 1 and 8). That is, any valve release is not actuated automatically and immediately. Instead, when the canister 73 of Genova reaches the bottom of the lower dwell chamber 94 it is held in place. This can present a risk if the user moves the device during the time when the valve is open, i.e. if the inhaler is no longer in the position required for effective filling of the metering chamber. For example, the user may move the inhaler from the desired vertical fill position to a horizontal position during this temporary blocking. An exemplary embodiment of the present invention which provides for automatic and immediate valve release can avoid such a problem.

In view of the above, Applicant submits that claim 1 is allowable over Genova. Claims 2-4 depend from claim 1 and are allowable at least by virtue of their dependency.

2. Claim 1 In View Of Casper et al. (US 5,826,571).

In rejecting claim 1 in view of Casper et al. (US 5,826,571), the grounds of rejection state:

The Casper et al. reference discloses an inhalation actuated device comprising a reservoir 12, a metering valve (unlabeled), an automatic trigger mechanism 28 and a brake device 30, as claimed.

Office Action at page 4.

In the claimed invention, the brake system acts in a predetermined manner (page 7, line 9), on the portion of the BAI that is movable (canister or valve), while the valve is being actuated, i.e. all along the actuation stroke. Indeed, according to an exemplary embodiment of the present application the effect of the brake begins as soon as the user actuates the device, as

described page 7, line 27 - page 8, line 2 and page 8, lines 15-19, and continuously goes on until the end of the actuating stroke of the valve member, where the effectiveness of the brake is at a maximum (page 9, lines 1-8). This extends the time during which the metering chamber can be emptied.

In contrast to the claimed invention, Casper only provides slowing of the actuating movement during a later portion of the actuation. Particularly, viscoelastic means which serve to slow the downward actuating movement take effect only after venting of the aerosol canister has begun and proceeded to a midway point (column 6, lines 25-26). The canister, upon actuation, moves downward and the metering chamber begins to vent its content without being slowed by the viscoelastic element. The canister continues its downward movement until rod 32, by means of an associated "stop", contacts viscoelastic element 36. The point of contact with viscoelastic element 36 coincides with a point intermediate between the position at which the metering chamber has begun to vent and the point at which the aerosol canister valve spring is fully compressed at its "bottom out position". Accordingly, any slowing down of the canister movement occurs only in a later portion of an actuation stroke.

In view of the above, Applicant submits that claim 1 and its dependents are also allowable over Casper.

An exemplary embodiment of a system according to present invention guarantees that the metering chamber of the valve is completely emptied at each actuation and provides an optimal accuracy of the dose metering thanks to an actuating stroke which is braked in a continuous and predetermined way (contrary to the cited references), and this even with the use of a valve-release system, and without the drawback of Genova or Casper, i.e. a pump staying open during a predetermined time.

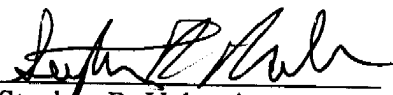
Furthermore it would not have been obvious for a person skilled in the art to combine Genova and Casper to reach the claimed invention as the structure and functioning of these disclosures completely differ making it impossible to combine them. Particularly, the object of Genova is to maintain the valve during a certain period of time (about 10 ms to 4 s) in a depressed position. On the contrary, the object of Casper is to make the valve return as quickly as possible in its rest position when it has reached its dispensing position. The objects of Genova and Casper are thus completely opposed, and a person skilled in the art would not combine them, since both Genova and Casper dissuade him to make such a combination.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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Giuseppe STRADELLA

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